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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,679	04/08/2004	Ian Hunter	65689CPDV(43382)	8534

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EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
06/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,679	HUNTER ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,9,12 and 17-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9,12 and 17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 3, 9, 12 and 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Macario (US 4,682,890) in view of Little (US 6,024,925), Lancaster (US 3,568,735) or Salomaa (US 4,478,094, both newly cited and applied). In the patent de Macario describes a carrier and a microsample holder (30) for use in horizontal beam spectrophotometers in place of conventional cuvette supports that normally are used with such spectrophotometers. The microsample holder is formed as a plate having a number of retaining elements preferably in the form of a circular perforated areas for retaining drops of samples to be analyzed by the spectrophotometer. Columns 2-3 teach a sample holder of similar design is known for vertical beam spectrometers. Columns 7-8 teach that the holder (30) is formed with a set of retaining elements, such as a row of four retaining elements (32,34,36,38). The retaining elements are of circular shape having diameters on the order of about 3 mm, each retaining element being capable of retaining a 5-10 μl sample of liquid to be analyzed. The surfaces of holder (30) other than the circular areas may be coated with a thin layer of hydrophobic material to assure retention of the liquid samples within the circular areas. The circular hole diameter permits the surface tension of the liquid sample to retain that sample stably within the confines of the hole. The remainder of holder (30) need not be light transmissive, it is, nevertheless, advantageous to its construction to construct the plate of transparent material, such as glass, plastic, quartz or the like. The holder (30) may be modified within the scope of the invention to have two or more

rows of retaining elements, if desired, such as the rectangular pattern shown in figure 5 and described in column 7, lines 45-61 or column 11, lines 6-28. It is recognized that the holder is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam spectrophotometers to pass through the center of each sample retained by retaining elements. In this respect the paragraph bridging columns 7-8 teaches that since the overall height, length and width of the carrier are identical (or substantially identical) to the height, length and width of the conventional cuvette support, the carrier is readily usable with the normal support-receptacle and automatic or manual indexing mechanism of conventional horizontal beam spectrophotometers. Thus, the retaining elements are aligned with the analyzing beam that normally passes through windows of the conventional cuvette support. It is seen that the analyzing beam thus passes through the center of each sample retained by retaining elements. The beam passes through only one sample at a time, and as the carrier is indexed, and successive samples are exposed to the beam. The patent also teaches that the de Macario device is meant to reduce the amount of sample required for the testing. The paragraph bridging columns 10-11 teaches the addition of reagents and samples to the holes of the device. In particular figure 8 and its associated description in column 10 teach registration of a plurality of carriers with a nonzero distance between them such that when fluid is added to one of the retaining elements a liquid bridge is formed between retaining elements on adjacent plates so that fluid is transferred between the registered through-holes in the carriers. In particular the carriers may have multiple aligned retaining elements on each carrier. Column 10, lines 42-54 teach that the carriers may also be used with vertical beam spectrometers along with several advantages relating to sample size and ease of preparation. de Macario does not teach the use of an array of transfer members to add fluids to the registered through-holes.

In the patent Lancaster teaches a laboratory dispensing apparatus including a base, a liquid reservoir and well assembly mounted rearward the base, and a microtitration plate carrier device mounted on the base for horizontal movement between a forward retracted position and a rearward operative position overlying a portion of the well. A novel vertically movable dispensing assembly having an array of transfer members/dispensers is positioned above the base in operative alignment with the portion of the liquid well so that with the carrier in the forward retracted position the dispensed assembly may withdraw microquantities of liquid from the well

and then dispense the same into the microtitration plate wells when the carrier is moved to the rearward position. The dispensing unit includes a novel pump piston actuator assembly and pneumatic control system which enable microquantities of liquid to be simultaneously and accurately picked up and dispensed from the dispensing needles or pipettes. Figure 1 shows a two dimensional configuration of transfer members while figure 18 shows a one-dimensional array of transfer members that transfers and dispenses fluid one row at a time. Figures 12-13 show an alternate form of the well. In the background section of column 1 discusses the amount of labor and time it took with prior manual processes and the use of automation to reduce the time and improve the accuracy.

In the patent Salomaa teaches an automatic liquid transfer system including a horizontally translatable table and a vertically translatable set/array of pipettes. The table accommodates a titer tray having a multiplicity of receptacles to be filled, or holding liquid samples to be diluted, and a rack housing plural rows of disposable tips. During each cycle in a serial dilution process, a fresh set of tips are picked up by the pipettes and used to transfer liquid in a sterile manner from a sample or diluent source to a row of wells in the titer tray, or from one row to a succeeding row of wells where it is mixed with diluent. Thereafter, the tips are discharged back into the rack to maintain sterile conditions during the process. A sensor is provided on the machine to detect whether all of the tips in each set are disengaged and another set successfully picked up. Figures 6-7 show different arrangements of the microtiter trays. Figure 12 is a perspective view of an alternate embodiment of a serial dilution machine including a fluid transfer or supply tray between the tip supply tray and the microtiter tray. This embodiment includes another microtiter tray (88) between sample tray (54) and tip supply tray (56). Tray 88 may contain either a liquid supply of biological material or a reagent for initially filling the titer tray receptacles. Columns 1-2 discuss the prior art and disclose that the invention was instituted to reduce the amount of time it took to perform the fluid transfers.

In the Little patent a system and method for preparing low volume analyte arrays is taught. The system includes serial and parallel dispensing tools that can deliver defined and controlled volumes of fluid to generate multi-element arrays of sample material on a substrate surface. The substrates surfaces can be flat or geometrically altered to include wells of receiving material. In one embodiment, the invention provides a tool that allows the parallel development

of a sample array. To this end, the tool can be understood as an assembly of vesicle elements, or pins, wherein each of the pins can include a narrow interior chamber suitable for holding manual liter volumes of fluid. Each of the pins can fit inside a housing that forms an interior chamber. The interior chamber can be connected to a pressure source that will control the pressure within the interior chamber to regulate the flow of fluid within the interior chamber of the pins. Figures 5A-5D show one method for dispensing fluids. In this embodiment, the robotic assembly (16) employs a pin tool assembly (38) that is configured similarly as the pin tool assembly (50) depicted in figure 2. In a first step, (figure 5A), the program can direct the robotic assembly to move the pin assembly above the source plate (20). The robotic assembly will then dip the pin assembly into the source plate (e.g. a 384 well plate). As shown in figure 4 the pin assembly can include 16 different pins such that the pin assembly will dip 16 pins into different 16 wells of the 384 well DNA source plate. Next, the data processor (12) will direct the motion controller (14) to operate the robotic assembly to move the pin assembly to a position above the surface of the substrate (34). The substrate can be any substrate suitable for receiving a sample of material and can be formed of silicon, plastic, metal, or any other such suitable material. The program can then direct the robotic assembly, to eject fluid from into a respective well (92) of the substrate (90). The data processor can run a computer program that controls and regulates the volume of fluid dispensed. The program can direct the controller to eject a defined volume of fluid, either by generating a spray or by forming a drop that sits at the end of the vesicle, and can be contacted with the substrate surface for dispensing the fluid thereto. Figures 5C and 5D show the earlier steps shown in figures 5A-5B can again be performed, this time at a position on the substrate surface that is offset from the earlier position. In the depicted process, the pin tool is offset by a distance equal to the distance between two wells. Another way of looking at it is that the well spacing of the substrate is an integral fraction of the well spacing in the source plate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the de Macario device in the form of an array as taught by de Macario of the size taught by Lancaster or Salomaa to provide an array of through-holes to contain sample and use the method of registration of two or more plates as taught by de Macario to add fluid to the holes through a liquid bridge as taught by de Macario using an array of pipettes or needles as taught by Lancaster or Salomaa because of the time reduction through using an array of pipettes

as taught by Lancaster and Salomaa and the ability to fill more than one carrier which would have been recognized by one of ordinary skill in the art as leading to a reduction in time. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to use a through-hole array as shown by Little which is an integral fraction of the spacing of the original source plate in the de Macario method because of the time benefits as noted above and a clear expectation that the fluid could be placed in a subset of the wells as shown by Little.

3. Applicant's arguments filed May 3, 2010 have been fully considered but they are not persuasive. The only real argument is that de Macario does not anticipate the claim language relative to the formation and breaking of a fluidic bridge because it does not specifically state that that is what happens and that this is not corrected by the secondary references. Examiner strongly disagrees with applicant's analysis for the following reason, how can fluid be transferred between two registered through-holes in two spaced apart carriers without the formation of a fluidic bridge as claimed? A reference is not required to specifically state that something which inherently happens is happening. Thus just because it doesn't mention hydrophilic surfaces or the formation and breaking of a fluidic bridge, does not mean that it does not happen. Applicant has not provided a plausible explanation of how the fluid transfer occurs and stops in de Macario without such a fluidic bridge both forming and breaking. Relative to the hydrophilic surface the paragraph bridging columns 2-3 clearly teaches that the plate is a glass plate with a coating of a hydrophobic material. Also the samples of de Macario are aqueous and would not stick to a hydrophobic surface. Page 8, lines 27-30 and page 16 lines 9-20 of the instant specification clearly teach glass of various compositions as a material used to form the plates. Thus the hydrophilic surface is also an inherent property of the de Macario reference. As a result, the only thing that de Macario is missing is the multiple transfer members. This aspect is clearly shown to be obvious by the teachings of the secondary references.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797